

# Notice of Allowability

Application No.

09/578,363

Examiner

Jeffrey E. Russel

Applicant(s)

WALLNER ET AL.

Art Unit

1654

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed December 19, 2003.
2. ☒ The allowed claim(s) is/are 1-8, 11-19, 31 and 36-81.
3. ☒ The drawings filed on 25 May 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |                                                                                                                        |                                                                                          |
|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                             | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>0104</u> |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. <u>1203</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                       |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material                 | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                 |
|                                                                                                                        | 9 <input type="checkbox"/> Other                                                         |

Art Unit: 1654

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2003 has been entered.

#### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Originally-numbered claims 56, 59, and 63 (re-numbered claims 39, 42, and 46, respectively) have been amended to correct their dependencies:

56. (Currently Amended) The pharmaceutical preparation method of claim 36 ~~44~~, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon- $\alpha$ 2a, Interferon- $\alpha$ 2b, Interferon- $\alpha$ n3, Interferon- $\gamma$ 1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate, Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegaspargase, Pentostatin, Prednimustine, Porfimer

Art Unit: 1654

sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

59. (Currently Amended) The method of claim 58 44, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon- $\alpha$ 2a, Interferon- $\alpha$ 2b, Interferon- $\alpha$ n3, Interferon- $\gamma$ 1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate, Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegasparase, Pentostatin, Prednimustine, Porfimer sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

63. (Currently Amended) The method of claim 62 44, wherein the anti-cancer compound is Aldesleukin, Asparaginase, Bleomycin Sulfate, Carboplatin, Chlorambucil, Cisplatin, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Dactinomycin, Daunorubicin hydrochloride, Docetaxel, Doxorubicin, Doxorubicin hydrochloride, Epirubicin hydrochloride, Etoposide, Etoposide phosphate, Floxuridine, Fludarabine, Fludarabine phosphate, Fluorouracil, Gemcitabine, Gemcitabine hydrochloride, Hydroxyurea, Idarubicin Hydrochloride, Ifosfamide, Interferons, Interferon- $\alpha$ 2a, Interferon- $\alpha$ 2b, Interferon- $\alpha$ n3, Interferon- $\gamma$ 1b, Interleukins, Irinotecan, Mechlorethamine hydrochloride, Melphalan, Mercaptopurine, Methotrexate,

Art Unit: 1654

Methotrexate sodium, Mitomycin, Mitoxantrone, Mitoxantrone hydrochloride, Paclitaxel, Pegaspargase, Pentostatin, Prednimustine, Porfimer sodium, Procarbazine Hydrochloride, Taxotere, Teniposide, Topotecan Hydrochloride, Vinblastine Sulfate, Vincristine Sulfate or Vinorelbine tartrate.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Maria A. Trevisan on January 22 and 23, 2004.

The provisional obviousness-type double patenting rejection set forth in paragraph 4 of the Office action mailed July 16, 2003 is withdrawn consistent with the procedures set forth in MPEP 822.01.

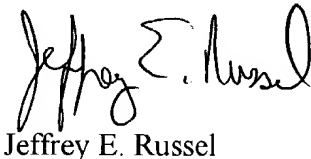
Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth in the Office action mailed July 16, 2003, paragraph 1. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

The supplemental declaration filed December 19, 2003 is not deemed to satisfy the above requirement because the supplemental declaration improperly refers to the amendment filed June 13, 2003 which contains new matter and because the supplemental declaration does not contain a statement that the inventor believes himself or herself to be the original, first, and joint inventor. See MPEP 602.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

January 23, 2004